

WATER BOTTLING PLANT LICENSE APPLICATION
(In-State or Out-of-State Bottler)

INSTRUCTIONS: A separate application ***submitted in duplicate*** is required ***for each place of business***. The fee for each ***renewal*** or ***new*** application in the sum indicated below payable to the **DEPARTMENT OF HEALTH SERVICES** must accompany this application. Unsigned or incomplete applications cannot be processed. **For *renewal* applications**, please indicate the license number on the top right-hand corner of your check and on this application. Please submit original and duplicate applications with the appropriate fee to:

Department of Health Services
Food and Drug Branch
P.O. Box 942832
Sacramento, CA 94234-0006

Check one box that applies for 2003 application fee **(PCA Code 85125)**

Fee for **New** Water Bottling Plant: ☐ \$1,248.11

Fee for **Renewal** Water Bottling Plant: ☐ If less than 5,000 gallons per week \$442.17

☐ If more than 5,000 gallons per week \$1,248.11

Type of application (check one): ☐ In-State ☐ Out-of-State

Check one: ☐ New ☐ Amended ☐ Renewal—license number: _____

Name of firm _____

DBA (if appropriate) _____

County where the bottling plant is located _____

Business address (number, street) (actual bottling plant location) _____

City _____

State _____

ZIP code _____

Telephone _____

()

Mailing address (if different from above) (P.O. Box/street address) _____

City _____

State _____

ZIP code _____

Emergency phone _____

()

Person responsible for operations _____

Correspondent _____

Bottled Water Products (Check box/attach labels.)

☐ A—Drinking

☐ E—Fluoridated

☐ I—Carbonated (sparkling)

☐ B—Distilled

☐ F—Flavored

☐ J—Purified by deionization

☐ C—Mineralized

☐ G—Spring

☐ K—Purified by reverse osmosis

☐ D—Mineral

☐ H—Artesian well

☐ L—Well (non-Artesian)

☐ M—Other (describe): _____

Average weekly water gallonage production for last year** (renewal application only):

** Average weekly production is determined by dividing the total number of gallons either produced in or shipped into California by 52.

List all product brand names bottled at your facility. (Attach labels—attach separate sheet if more space is needed.)

_____	_____	_____
_____	_____	_____
_____	_____	_____

Your water source(s) is from: ☐ Private water ☐ Public water

Water source is: ☐ In-State—Include California Private Water Source Operator license number(s)

☐ Out-of-State—include the description of the exact location of the source(s)

Name of private source(s) or water district _____

California Private Water Source Operator
license number(s) _____

Telephone _____

()

Address (number, street) _____

City _____

State _____

ZIP code _____

Description of the exact location of the source(s): _____

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Were any changes made from the previous application (renewal application only)?

☐ Yes

☐ No

If yes, please explain:

Type of Ownership

☐ Partnership

☐ Association

☐ Corporation

☐ Individual/sole proprietorship

☐ Other (describe): _____

If individual or sole proprietorship:

Name of individual or sole proprietor

Name of business entity (DBA)

If a partnership or unincorporated association:

Name of the partnership or unincorporated association

Name of each partner or member

If a corporation:

Name of corporation

Name of state of incorporation

Name and title of each corporate officer and corporate director

The Food and Drug Branch ***must be notified immediately*** of any change in the above information. If any changes were made, explain on a separate sheet.

Under penalty of perjury, under the laws of the State of California, the person whose signature appears below certifies and says that: (1) he/she is the applicant, or one of the applicants, or an executive officer of the applicant corporation, named in the foregoing application, duly authorized to make this application on its behalf; (2) he/she has read the foregoing application and knows the contents thereof and that each and all statements therein made are true; (3) no person other than the applicant or applicants has any direct or indirect interest in the applicant's business to be conducted under the license for which this application is made; and (4) all supplemental statements are true and accurate.

Signature of applicant

Date

Print name

Title

PROCEDURE FOR OBTAINING AN *IN-STATE* WATER BOTTLING PLANT LICENSE

California Health and Safety Code (H&SC) Section 111120 requires that a bottler obtain a license issued by the Department of Health Services' Food and Drug Branch (FDB) to operate a water bottling plant in California. The following describes what you must do to help us issue your license as quickly as possible.

License Application

Submit a completed application form in duplicate to the address shown on the application together with the required fee, which is nonrefundable. The license is valid for one calendar year and expires on December 31. The business address must be that of the **bottling plant**, not that of the corporate headquarters. The mailing address can be either that of the plant, corporate headquarters, or the firm's branch office (the license will be mailed to the mailing address). Any incomplete and/or illegible application will be RETURNED to the applicant, which would result in a significant delay in the processing of that application.

FDB will perform an on-site inspection of the plant before issuing a license to assure that the bottling facility meets the requirements specified in Part 129 of Title 21 of the Code of Federal Regulations (21 CFR), and other state and federal laws. Please contact one of the nearest FDB offices (see the last page of this procedure) for a phone number to call for an appointment for inspection.

NOTE: Submit the information specified below (items 1, 2, 3 and 4), in duplicate, to the Food and Drug Investigator at the time of inspection of your facility.

Information Required at the Time of Inspection

1. Water Source: All water sources must be identified on the application form. Only water from licensed sources or approved public drinking (or municipal) water districts can be processed for bottling.
 - a. If an unlicensed private well or spring source is the source of the water supply and the well or source is based and operated at the same location as the bottling plant, submit also a completed Private Water Source Operator's (PWSO) license application form, in duplicate, together with all required supporting documents and information as specified in the "Procedure For Obtaining A Private Water Source Operator License." The license application fee for the PWSO license may be waived pursuant to H&SC, Section 111120. Please contact the Water Licensing Desk, (916) 323-4774, to obtain the PWSO license application form, procedures, and the list of substances to be analyzed.
 - b. If the source is currently licensed for the sale of the particular water, provide the source information. The information must include name of the source owner, purchase contract, location of the source, license number, and telephone number of the PWSO.
 - c. If the source is neither currently licensed and not located at the site of bottling plant, a PWSO license application must be submitted with the application fee and required documents/information as indicated in the "Procedure for Obtaining a Private Water Source Operator License."
 - d. If public drinking (or municipal) water is used as a source, provide the name of the Water District, address, telephone number, and a copy of the Water District's most recent chemical, physical and microbiological analysis data for the water.
2. Analytical Tests Required (If you bottle more than one type of products at the facility, you must submit multiple sets of analysis for each product. Please contact Water Licensing Desk at (916) 323-4774 for a copy of the list for substances to be analyzed.)
 - General chemical, physical, and radiological quality of water as required by the federal quality standards of bottled water and H&SC, Sections 111080 and 111155 (see the attachment, Group I, II, III, and V for specific substances). The test report should be valid for one year from the date of analysis.
 - Bacteriological quality of water as required by the federal quality standards of bottled water (Group IV).

NOTE: All testing must be done by a California certified water laboratory (Please contact California Environmental Laboratory Accreditation Program at (510) 540-2800 for the list of locations and phone numbers of certified laboratories) or by a laboratory certified by the United States Environmental Protection Agency (USEPA). Testing done by a laboratory approved by a primary enforcement authority in states which have been granted primacy by the USEPA is acceptable according to H&SC Section 111165.

3. Bottling Operation

- Schematic site (facility) diagram;
- Schematic water treatment/bottling process diagram;
- Evidence (attach photographs) whether the facility has a separate bottling room in compliance with the requirement of 21 CFR 129.20(a);
- Indication whether the bottling room is operated in a sealed system under pressure;
- Specifications of equipment (please do not send copies of promotional material or advertisements; state on the top of the first page of each specification sheet whether the equipment has been approved for food and/or potable water use, and the approval organization);
- Sanitation procedure;
- Information on your "unit package production code" as required by 21 CFR Part 129. (We suggest that a copy of your "recall plan," which includes the production code information, be submitted.);
- Information on your record keeping as required by 21 CFR Part 129 (We suggest that a copy of your "product quality control procedure," which includes the record keeping information, be submitted);
- Photographs showing the bottling equipment and facility.

4. Labels and Promotional Materials

Submit labels (original; not photocopies), advertising, and promotional materials (original; not photocopies). Typed or photocopied labels may be submitted with prior approval of FDB only if the labels are: (1) printed or embossed directly on bottles, or (2) large labels (greater than 100 square inches in label size) printed directly on large boxes. Labels, advertising, and promotional materials must meet the requirements of H&SC, Section 109875 et seq., and applicable federal regulations (including those for nutrition labeling if nutrient content or health claims are made or if nutrition information which triggers nutrition labeling is provided).

Food and Drug Branch Offices

FDB Water Licensing Desk

601 North Seventh Street (MS 357)
P.O. BOX 942732
Sacramento, CA 94234-7320
Telephone: (916) 323-4774
Fax: (916) 322-6326

FDB Los Angeles Office

1449 West Temple Street, Room 224
Los Angeles, CA 90026
Telephone: (213) 580-5720
Fax: (213) 580-5750

PROCEDURES FOR OBTAINING AN *OUT-OF-STATE* WATER BOTTLING PLANT LICENSE

California Health and Safety Code (H&SC) Sections 111070 to 111195 include provisions that require an out-of-state or foreign bottler to obtain a license issued by the California Department of Health Services' Food and Drug Branch (FDB) to distribute bottled water or vended water in California. The following describes what you must do to help us issue your license as quickly as possible. Please submit:

1. A completed application form together with the required fee, which is nonrefundable. The license is valid for one calendar year and expires on December 31. The business address must be that of the out-of-state **bottling plant**, not that of the corporate headquarters. The mailing address can be either that of the corporate headquarters or the firm's branch office (the license will be mailed to the mailing address). Any incomplete and/or illegible application will be RETURNED to the applicant, which would result in a significant delay in the processing of that application.
2. Copies of valid bottling plant and water source licenses, certificates or permits issued by the state or country agency which has jurisdiction over the out-of-state (or foreign) plant and water source.

3. Water Source

If a private well or spring is the source of the water:

- a. Information from a licensed (or certified) Hydrogeologist, Geologist, Engineering Geologist, or Hydrogeological Engineer:
 - Description of the exact source location; and a detail map (if not available, a drawing) showing the boundary and the location of the natural spring (if applicable), bore hole (if applicable), well (if applicable), buildings, storage tank and piping.
 - A review of the hydrogeology surrounding the site including a description of the vertical and horizontal extent of the source aquifer.
 - Information on the recharge area or zone of influence of the subject source, and that identifies and evaluates actual and potential sources of contamination.
 - Details of the source development: description and/or diagrams of the method of construction, collection and catchment of source water, storage facility, conveyance and loading systems, underground piping map, and treatment systems used. All equipment must have documented proof that they have been approved for potable water use.
 - If ground water (e.g., spring water, artesian well water, well water), evidence (e.g., microscopic particulate analysis) that it is not under the direct influence of surface water as defined in 40 CFR 141.2.
 - Substantiating information that the designation of source water (e.g., "spring water," "artesian well water," "well water") meets the definition for the term as specified in H&SC Section 111175 and 21 CFR Section 165.110(a)(2)(vi).
- b. Information from the state, local health agency, or other approval authority:
 - Copies of well (bore hole) driller's report and/or well (bore hole) log; well (bore hole) sealing diagram; certificate or permit for satisfactory well construction from the pertinent state or local agency.
 - Sanitary appraisal report for the well or spring.
- c. If your source is a spring and the spring water is extracted from a bore hole(s) using external force, you must provide the following information as well:
 - An explanation why a bore hole(s) is used;
 - Evidence including actual data that: (1) water flows naturally to the surface of the earth at the natural spring (a copy of the inspection report from the pertinent government agency); (2) spring water collected from the bore hole is from the same underground stratum as the natural spring, as shown by a measurable hydraulic connection (using a hydrogeologically valid method such as the pumping test, dye test) between the bore hole and the natural spring; (3) water from the bore hole has all the physical properties, before treatment, and is of the same composition and quality as the water that flows naturally to the surface of the earth (i.e., natural spring).

d. Samples for testing:

- All testing must be done on samples collected after completion of the entire system (e.g., well drilling, piping, installation of storage tanks, loading system).
- If multiple sources feed into a common distribution system, only the sample from the common system rather than each source can be tested, provided that the sources have already been approved. For a new license, however, each source must be analyzed separately.

e. Photographs of the source showing its construction, surrounding area, storage facility, conveyance and loading systems, and treatment systems used.

If public or municipal water is used as a source:

Provide the name of the water district, address, telephone number, and a copy of the water district's most recent chemical, physical, radiological, and microbiological analysis data for the water.

4. Analytical tests required: (You must submit two sets of analysis, one for source water and another for product water. If you have multiple sources and/or multiple types of products to be bottled at the facility, you must submit multiple sets of analysis for each source and each product. Please contact Water Licensing Desk at (916) 323-4774 for the lists of substances to be analyzed.)

- General chemical, physical, and radiological quality of water as required by the federal quality standards for bottled water and H&SC, Sections 111080, 111150, and 111155 (Group I, II, III, and V). The test results should be valid for one year from the date of analysis.
- Bacteriological quality of water as required by the federal quality standards of bottled water (Group IV).

NOTE: All testing must be done by a California certified water laboratory (Please contact the California Environmental Laboratory Accreditation Program at (510) 540-2800 for the list of locations and phone numbers of certified laboratories) or by a laboratory certified by the United States Environmental Protection Agency (USEPA). Testing done by a laboratory approved by the primary enforcement authority in states which have been granted primacy by the USEPA is also acceptable pursuant to H&SC Section 111165.

5. Bottling Operation

- Schematic site (facility) diagram;
- Schematic water treatment/bottling process diagram;
- Evidence (attach photographs) whether the facility has a separate bottling room in compliance with the requirement of 21 CFR 129.20(a);
- Indication whether the bottling room is operated in a sealed system under pressure;
- Specifications of equipment (please do not send copies of promotional material or advertisements; state on the top of the first page of each specification sheet whether the equipment has been approved for food and/or potable water use, and the approval organization);
- Sanitation procedure;
- Information on your "unit package production code" as required by 21 CFR Part 129 (We suggest that a copy of your "recall plan," which includes the production code information, be submitted.);
- Information on your record keeping as required by 21 CFR Part 129 (We suggest that a copy of your "product quality control procedure," which includes the record keeping information, be submitted);
- Photographs showing the bottling equipment and facility.

6. Labels and promotional materials: Submit labels, advertising and promotional materials (original; not photocopies). Typed or photocopied labels may be submitted with prior approval of FDB only if the labels are: (1) printed or embossed directly on bottles, or (2) large labels (greater than 100 square inches in label size) printed directly on large boxes. Labels, advertising, and promotional materials must meet the requirements of H&SC, Section 109875 et seq. and applicable federal regulations (including those of nutrition labeling if nutrient content or health claims are made or if nutrition information which triggers nutrition labeling is provided).

NOTE: Any new drilling or redeveloping of a source under this license will automatically trigger the revaluation of the source. You must contact us for reevaluation of the source and obtain an approval before using it.